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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,743	08/21/2007	Gyula Vigh		5360

Gyula Vigh
3369 Tamu
College Station, TX 77840

7590

09/27/2010

EXAMINER

BALL, JOHN C

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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09/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,743	Applicant(s) VIGH ET AL.	
	Examiner J. CHRISTOPHER BALL	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007 and 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office Action based on the VIGH et al. application filed under the Patent Cooperation Treaty on August 13, 2004, and presently a National Stage Application.
2. Claims 1-5, 7-25, and 27 are currently pending and have been fully considered.
3. The preliminary amendment filed with the Office on February 10, 2006, is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-11, 13, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by an article by OXFORD et al. ("Effect of Chelated Metal on Amino Acid Transport in Facilitated Transport Membranes Incorporating Metal Affinity", POLYMERIC MATERIALS SCIENCE AND ENGINEERING, vol. 77, 1997, p. 273-274), submitted to the Office on an Information Disclosure Statement.

Regarding claim 1, OXFORD teaches a hydrolytically stable isoelectric hydrogel material formed by mixing and/or reacting a mixture comprising:

a polyhydroxy compound, in the form of poly(vinyl alcohol) (first paragraph, "Membrane Preparation and Functionalization" section, p. 273);

a single isoelectric compound having a pI value from 1 to 12, in the form of an iminodiacetic acid (third paragraph, "I. Introduction" section, p. 273); and

a difunctional agent, in the form of 1,4-butanediol diglycidyl ether (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),

whereby after the mixing and/or reacting, the hydrolytically stable isoelectric hydrogel material formed inherently becomes an ampholytic material.

Regarding claim 2, OXFORD teaches the hydrolytically stable isoelectric hydrogel material has a pI value which does not substantially change when the amount of the isoelectric compound mixed and/or reacted is altered, in that iminodiacetic acid has an intrinsic pI value that would be imparted to the hydrolytically stable isoelectric hydrogel material and is present in excess of that required to establish the pH of the hydrogel substantially equal to said pI (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

Regarding claims 3 and 4, OXFORD teaches the single isoelectric compound is iminodiacetic acid (third paragraph, "I. Introduction" section, p. 273).

Regarding claim 7, OXFORD teaches the difunctional agent consists of diepoxide, in the form of 1,4-butanediol diglycidyl ether (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

Regarding claim 8, OXFORD teaches a hydrolytically stable isoelectric hydrogel material formed by mixing and/or reacting a mixture comprising:

- an isoelectric compound having a pI value from 1 to 12, in the form of an iminodiactetic acid (third paragraph, "I. Introduction" section, p. 273); and
- a polymer scaffold, in the form of poly(vinyl alcohol) (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),

wherein the hydrolytically stable isoelectric hydrogel material form thereby can be turned into a membrane (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),

whereby after the mixing and/or reacting, the hydrolytically stable isoelectric hydrogel material formed inherently becomes an ampholytic material.

Regarding claim 9, OXFORD teaches the hydrolytically stable isoelectric hydrogel material has a pI value which does not substantially change when the amount of the isoelectric compound mixed and/or reacted is altered, in that iminodiactetic acid has an intrinsic pI value that would be imparted to the hydrolytically stable isoelectric hydrogel material and is present in excess of that

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required to establish the pH of the hydrogel substantially equal to said pI (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

Regarding claims 10 and 11, OXFORD teaches the single isoelectric compound is iminodiacetic acid (third paragraph, "I. Introduction" section, p. 273).

Regarding claim 13, OXFORD teaches the polymer scaffold consists of poly(vinyl alcohol) (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

Regarding claims 21 and 22, OXFORD teaches a hydrolytically stable hydrogel membrane comprising the hydrolytically stable isoelectric material outline in the rejection of claim 1 above (first paragraph, "Membrane Preparation and Functionalization" section, p. 273) supported on a crosslinkable poly(vinyl alcohol) membrane (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

Regarding claim 23, OXFORD teaches a method of forming a hydrolytically stable isoelectric hydrogel material formed by mixing and/or reacting a mixture comprising:

a polyhydroxy compound, in the form of poly(vinyl alcohol) (first paragraph, "Membrane Preparation and Functionalization" section, p. 273);

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a single isoelectric compound having a pI value from 1 to 12, in the form of an iminodiactetic acid (third paragraph, "I. Introduction" section, p. 273); and
a difunctional agent, in the form of 1,4-butanediol diglycidyl ether (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),
whereby after the mixing and/or reacting, the hydrolytically stable isoelectric hydrogel material formed inherently becomes an ampholytic material.

Regarding claim 24, OXFORD teaches a method of forming a hydrolytically stable isoelectric hydrogel material formed by mixing and/or reacting a mixture comprising:

an isoelectric compound having a pI value from 1 to 12, in the form of an iminodiactetic acid (third paragraph, "I. Introduction" section, p. 273); and

a polymer scaffold, in the form of poly(vinyl alcohol) (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),

wherein the hydrolytically stable isoelectric hydrogel material form thereby can be turned into a membrane (first paragraph, "Membrane Preparation and Functionalization" section, p. 273),

whereby after the mixing and/or reacting, the hydrolytically stable isoelectric hydrogel material formed inherently becomes an ampholytic material.

Regarding claim 25, OXFORD teaches a method of forming a hydrolytically stable hydrogel membrane comprising the hydrolytically stable

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isoelectric material outline in the rejection of claim 1 above (first paragraph, “Membrane Preparation and Functionalization” section, p. 273) supported on a crosslinkable poly(vinyl alcohol) membrane (first paragraph, “Membrane Preparation and Functionalization” section, p. 273).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article by OXFORD et al. (“Effect of Chelated Metal on Amino Acid Transport in Facilitated Transport Membranes Incorporating Metal Affinity”,

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POLYMERIC MATERIALS SCIENCE AND ENGINEERING, vol. 77, 1997, p. 273-274), submitted to the Office on an Information Disclosure Statement.

Regarding claims 14 and 17, OXFORD teaches the hydrolytically stable isoelectric material is formed by reacting iminodiacetic acid, poly(vinyl alcohol), and 1,4-butanediol diglycidyl ether in the presence of NaOH (first paragraph, “Membrane Preparation and Functionalization” section, p. 273).

OXFORD does not explicitly teach either glycerol diglycidyl ether or poly(ethylene glycol) diglycidyl ether.

However, both glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether are homologous compounds to 1,4-butanediol diglycidyl ether, and it would have been obvious to one of ordinary skill in the art expect success when substituting either glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether for 1,4-butanediol diglycidyl ether in the composition of the hydrolytically stable isoelectric material (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

9. Claims 5, 12, 15, 16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article by OXFORD et al. (“Effect of Chelated Metal on Amino Acid Transport in Facilitated Transport Membranes Incorporating Metal Affinity”, POLYMERIC MATERIALS SCIENCE AND ENGINEERING, vol. 77,

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1997, p. 273-274) in view of RATNER et al. (WO 03/059965 A1), both submitted to the Office on an Information Disclosure Statement.

Regarding claims 5 and 12, OXFORD teaches the limitations of claims 1 and 8, as outlined above. OXFORD teaches the isoelectric compound is iminodiacetic acid (third paragraph, "I. Introduction" section, p. 273).

OXFORD does not teach the isoelectric compound is selected from the group consisting of diaminocarboxylic acids, diaminophenols, diaminophosphonic acids, oligoaminocarboxylic acids, oligoaminophenols, oligoaminophosphonic, and compounds containing combinations of the functional groups thereof.

However, RATNER discloses hydrogels, wherein is taught a hydrogel containing an isoelectric compound in the form of tryptophan (p. 6, lines 29-32), which is a diaminocarboxylic acid compound.

At the time of the present invention, it would have been obvious is that the substitution of one known isoelectric compound element, tryptophan, for another isoelectric compound, iminodiacetic acid, yields predictable results to one of ordinary skill in the art (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

Regarding claims 15 and 18, OXFORD teaches the limitations of claim 8, as outlined above. Additionally, OXFORD teaches the hydrolytically stable isoelectric material is formed by reacting iminodiacetic acid, poly(vinyl alcohol),

and 1,4-butanediol diglycidyl ether in the presence of NaOH(first paragraph, “Membrane Preparation and Functionalization” section, p. 273).

OXFORD does not explicitly teach either glycerol diglycidyl ether or poly(ethylene glycol) diglycidyl ether.

However, both glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether are homologous compounds to 1,4-butanediol diglycidyl ether, and it would have been obvious to one of ordinary skill in the art expect success when substituting either glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether for 1,4-butanediol diglycidyl ether in the composition of the hydrolytically stable isoelectric material (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

OXFORD does not explicitly teach the isoelectric compound is aspartic acid.

However, RATNER discloses hydrogels, wherein is taught a hydrogel containing an isoelectric compound in the form of aspartic acid (p. 6, lines 29-32).

At the time of the present invention, it would have been obvious is that the substitution of one known isoelectric compound element, aspartic acid, for another isoelectric compound, iminodiacetic acid, yields predictable results to one of ordinary skill in the art (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

Regarding claims 16 and 19, OXFORD teaches the limitations of claim 8, as outlined above. Additionally, OXFORD teaches the hydrolytically stable isoelectric material is formed by reacting iminodiacetic acid, poly(vinyl alcohol), and 1,4-butanediol diglycidyl ether in the presence of NaOH (first paragraph, "Membrane Preparation and Functionalization" section, p. 273).

OXFORD does not explicitly teach either glycerol diglycidyl ether or poly(ethylene glycol) diglycidyl ether.

However, both glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether are homologous compounds to 1,4-butanediol diglycidyl ether, and it would have been obvious to one of ordinary skill in the art expect success when substituting either glycerol diglycidyl ether and poly(ethylene glycol) diglycidyl ether for 1,4-butanediol diglycidyl ether in the composition of the hydrolytically stable isoelectric material (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

OXFORD does not explicitly teach the isoelectric compound is glutamic acid.

However, RATNER discloses hydrogels, wherein is taught a hydrogel containing an isoelectric compound in the form of glutamic acid (p. 6, lines 29-32).

At the time of the present invention, it would have been obvious is that the substitution of one known isoelectric compound element, glutamic acid, for another isoelectric compound, iminodiacetic acid, yields predictable

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results to one of ordinary skill in the art (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

Regarding claim 20, OXFORD teaches the limitations of claim 8, as outlined above. Additionally, OXFORD teaches the hydrolytically stable isoelectric material is formed by reacting iminodiacetic acid, poly(vinyl alcohol), and 1,4-butanediol diglycidyl ether in the presence of NaOH (first paragraph, “Membrane Preparation and Functionalization” section, p. 273).

OXFORD does not explicitly teach either glycerol diglycidyl ether.

However, glycerol diglycidyl ether is a homologous compound to 1,4-butanediol diglycidyl ether, and it would have been obvious to one of ordinary skill in the art expect success when substituting glycerol diglycidyl ether for 1,4-butanediol diglycidyl ether in the composition of the hydrolytically stable isoelectric material (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

OXFORD does not explicitly teach the isoelectric compound is lysing.

However, RATNER discloses hydrogels, wherein is taught a hydrogel containing an isoelectric compound in the form of lysing (p. 6, lines 29-32).

At the time of the present invention, it would have been obvious is that the substitution of one known isoelectric compound element, lysing, for another isoelectric compound, iminodiacetic acid, yields predictable results to

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one of ordinary skill in the art (*KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over an article by OXFORD et al. ("Effect of Chelated Metal on Amino Acid Transport in Facilitated Transport Membranes Incorporating Metal Affinity", POLYMERIC MATERIALS SCIENCE AND ENGINEERING, vol. 77, 1997, p. 273-274), submitted to the Office on an Information Disclosure Statement, in view of LINDER et al. (US 5,430,099).

Regarding claim 27, OXFORD teaches a hydrolytically stable hydrogel membrane comprising a hydrolytically stable isoelectric material.

OXFORD does not teach a method of separating compounds by electrophoresis wherein the compound are introduced into a membrane-based electrophoresis apparatus.

However, LINDER discloses gels and membranes for isoelectric focusing, wherein is taught a membrane-based electrophoresis apparatus for separation of compounds (Figure 1; Col. 12, lines 11-14).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to combine the hydrolytically stable hydrogel membrane as taught by OXFORD with the membrane-based electrophoresis apparatus for

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separation of compounds as taught by LINDER because the membrane have a very narrow pH interval, so that identical membranes can be prepared (LINDER, Col. 12, lines 40-48), which is an advantage over IEF slab gels.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JCB
09/23/2010